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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, THIRD JUDICIAL DISTRICT**

**PATRICIA L. POWELL and
ROBERT B. POWELL,**

Plaintiffs,

v.

WRIGHT MEDICAL TECHNOLOGY, INC.,

Defendant.

**DEFENDANT WRIGHT MEDICAL
TECHNOLOGY, INC.'S ANSWER TO
PLAINTIFFS' COMPLAINT**

Case No. 2:20-cv-00306
Judge Robert J. Shelby

JURY TRIAL DEMANDED

Defendant Wright Medical Technology, Inc. ("WMT" or "Wright Medical") files this Answer and Affirmative Defenses to Plaintiffs Patricia L. Powell's ("Plaintiff") and Robert B. Powell's Complaint and states as follows:

COMPLAINT FOR DAMAGES

With respect to the unnumbered paragraph entitled "Complaint For Damages," WMT denies the statements in the Paragraph because they are not factual averments, but instead, purport to describe the nature of Plaintiffs' action and the claims asserted. To the extent these statements are deemed factual or a response is required, WMT denies the allegations contained in this

Paragraph. Moreover, this Paragraph contains conclusions of law to which no responsive pleading is required.

NATURE OF ACTION

1. Denied. The allegations in this Paragraph are not factual averments, but instead, purport to describe the nature of Plaintiffs' action and the claims asserted. To the extent deemed factual or a response is deemed required, WMT denies the allegations contained in this Paragraph. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

2. Denied. WMT denies the allegations in this Paragraph and specifically denies that the DYNASTY® components "had a propensity to fail within a few years of implantation" or were defective in any way. With respect to Plaintiffs' allegations regarding Plaintiff's alleged injuries, WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

PARTIES

3. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

4. Admitted in part; denied in part. WMT admits that it is incorporated in Delaware with its principal place of business in Tennessee. WMT denies all other allegations in this Paragraph. To the extent that the allegations in this Paragraph are conclusions of law, no responsive pleading is required.

5. Admitted in part; denied in part. WMT admits that at certain times it marketed, distributed, and/or sold certain prosthetic orthopedic products including the components allegedly at issue in this matter. Due to the vagueness of the term “at all relevant times,” WMT denies the remaining allegations in this Paragraph.

STATEMENT OF JURISDICTION AND VENUE

6. Denied. The allegations in this Paragraph constitute conclusions of law to which no responsive pleading is required, and the allegations are denied on this basis.

7. Denied. The allegations in this Paragraph constitute conclusions of law to which no responsive pleading is required, and the allegations are denied on this basis. To the extent a response is required, WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph concerning the location of the events allegedly giving rise to this claim and they are therefore denied.

8. Denied. The allegations in this Paragraph constitute conclusions of law to which no responsive pleading is required, and the allegations are denied on this basis. To the extent deemed factual or a response is deemed required, WMT denies the allegations contained in this Paragraph.

9. Admitted in part; denied in part. WMT admits that at certain times it marketed, distributed, and/or sold certain prosthetic orthopedic products including the type of components allegedly at issue in this matter. Due to the vagueness of the term “at all times relevant hereto,” WMT denies the remaining allegations in this Paragraph. Further, WMT specifically denies that the products alleged to be at issue were defective in any way.

FACTUAL ALLEGATIONS¹

A. The Device and Its Regulatory History

10. Admitted in part; denied in part. WMT admits only that it has at certain times marketed and sold certain hip replacement components throughout the United States, including the type of DYNASTY® device alleged to be at issue. WMT denies all other allegations in this Paragraph.

11. Admitted in part; denied in part. It is admitted only that WMT developed certain hip replacement products under the brand name DYNASTY®. WMT denies all other allegations in this Paragraph as mischaracterizations and overbroad generalizations.

12. Admitted in part; denied in part. WMT admits only that the type of DYNASTY® device alleged to be at issue is subject to regulation by the Food and Drug Administration. WMT denies all other allegations in this Paragraph as mischaracterizations and overstatements. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

13. Denied. WMT denies all allegations in this Paragraph as mischaracterizations and overbroad generalizations. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

14. Admitted in part; denied in part. WMT admits only that its TRANSCEND® device obtained 510(k) clearance from the FDA, and that the clearance was applied to the type of device

¹ To the extent any headings or sub-headings set forth in the Complaint contain, or are deemed to contain, any allegation against WMT or attempt to characterize other allegations against WMT, such allegations and characterizations are denied.

referred to as the CONSERVE® shell. WMT denies all remaining allegations in this Paragraph as mischaracterizations and overstatements. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

15. Admitted in part; denied in part. WMT admits only that its DYNASTY® device utilized an acetabular shell component. WMT denies all remaining allegations in this Paragraph as mischaracterizations and overstatements.

16. Denied. Plaintiffs' references to "Spiked Shell," "HA Shell," and "Thick Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

17. Denied. Plaintiffs' reference to "A-Class femoral head" is vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

18. Denied. WMT denies the allegations in this Paragraph. Further, Plaintiffs' references to the "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

19. Denied. WMT denies the allegations in this Paragraph as mischaracterizations.

B. Wright's History with the Device.

20. Admitted in part; denied in part. WMT admits only that it purchased Orthomet, Inc. WMT denies the allegations in this Paragraph as improper generalizations and mischaracterizations.

21. Admitted in part; denied in part. WMT admits only that it purchased Orthomet, Inc. WMT denies the remaining allegations in this Paragraph as improper generalizations and mischaracterizations.

22. Denied. The allegations in this Paragraph are directed to an entity other than WMT, therefore WMT is without knowledge or information sufficient to form a belief as to the truth of these allegations and they are denied on that basis. WMT further denies the allegations in this Paragraph as improper generalizations and mischaracterizations.

23. Denied. WMT denies the allegations in this Paragraph as improper generalizations and mischaracterizations.

24. Denied. WMT denies the allegations in this Paragraph as improper generalizations and mischaracterizations.

25. Denied. WMT denies the allegations in this Paragraph as improper generalizations and mischaracterizations.

26. Denied. The allegations in this Paragraph are directed to an entity other than WMT, therefore WMT is without knowledge or information sufficient to form a belief as to the truth of these allegations and they are denied on that basis.

27. Denied. The allegations in this Paragraph are directed to an entity other than WMT, therefore WMT is without knowledge or information sufficient to form a belief as to the truth of these allegations and they are denied on that basis.

28. Denied. WMT denies the allegations in this Paragraph as improper generalizations and mischaracterizations.

29. Denied. WMT denies the allegations in this Paragraph.

30. Denied. WMT denies the allegations in this Paragraph.

31. Denied. WMT denies the allegations in this Paragraph.

C. The Conserve Thin Shell Never Received PMA Approval and Was a Regulatory and Clinical Failure.

32. Admitted in part; denied in part. It is admitted only that a study was conducted using CONSERVE® Plus Total Resurfacing heads and CONSERVE® cups in the United States under IDE #G990328. WMT denies any remaining allegations in this Paragraph as mischaracterizations.

33. Admitted in part; denied in part. WMT admits that in 2003 it submitted a Pre-Market Approval submission for the CONSERVE® Plus Resurfacing Hip System. WMT denies the remaining allegations as mischaracterizations. Further, Plaintiffs' reference to "Thick Shell" is vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

34. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

35. Denied. The allegations in this Paragraph are directed towards a person other than WMT, therefore WMT is without knowledge or information sufficient to form a belief as to the truth of these allegations and they are denied on that basis. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

36. Denied. WMT denies the allegations in this Paragraph as mischaracterizations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

37. Denied. WMT denies the allegations in this Paragraph as mischaracterizations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

38. Denied. WMT denies the allegations in this Paragraph as mischaracterizations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

39. Denied. WMT denies the allegations in this Paragraph. Further, Plaintiffs' references to "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

40. Denied. WMT denies the allegations in this Paragraph as mischaracterizations. Further, Plaintiffs' references to "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

41. Denied. WMT denies the allegations in this Paragraph as mischaracterizations. Further, Plaintiffs' references to "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

42. Denied. WMT denies the allegations in this Paragraph and specifically denies that the "Thin Shell" had an "extraordinarily high revision rate." Further, Plaintiffs' references to "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

43. Denied. WMT denies the allegations in this Paragraph. Further, Plaintiffs' references to "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

D. Wright Obtained Pre-Marketing 510(k) Clearance For Some - But Not All - Conserve® Components.

44. Admitted in part; denied in part. WMT admits that certain DYNASTY® total hip devices were cleared via the 510(k) process. All other allegations in this Paragraph are denied. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

45. Denied. The allegations in this Paragraph constitute conclusions of law to which no responsive pleading is required and they are denied on this basis.

46. Denied. WMT denies the allegations in this Paragraph as imprecise characterizations. Further, this Paragraph refers to written materials, the terms of which speak for themselves and any characterizations thereof or inferences made are denied. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

47. Denied. The allegations in this Paragraph are directed towards a product which was not manufactured or sold by WMT, and WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

48. Denied. WMT denies the allegations in this Paragraph as mischaracterizations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

49. Denied. WMT denies the allegations in this Paragraph as mischaracterizations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

50. Admitted in part; denied in part. WMT admits that it obtained 510(k) clearance for its Metal TRANSCEND® Articulation System. WMT denies the remaining allegations in this Paragraph as imprecise characterizations.

51. Admitted in part; denied in part. WMT admits that the Metal TRANSCEND® Articulation System (Larger Sizes) received 510(k) clearance. WMT denies the remaining allegations as imprecise characterizations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

52. Admitted.

53. Denied. WMT denies the allegations in this Paragraph as mischaracterizations and overstatements.

E. Wright Dodged the FDA Through Inappropriate Use of a “Letter to File,” In Lieu Of the 510(k) Process, For the Conserve® Thin Shell.

54. Denied. WMT denies the allegations in this Paragraph as mischaracterizations and overbroad generalizations. Further, Plaintiffs’ references to “Thin Shell” are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

55. Denied. WMT denies the allegations in this Paragraph as mischaracterizations and overbroad generalizations. Further, Plaintiffs’ references to “Thin Shell” are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

56. Denied. WMT denies the allegations in this Paragraph as mischaracterizations and overbroad generalizations. Further, Plaintiffs’ references to “Thin Shell” are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

57. Denied. WMT denies the allegations in this Paragraph as mischaracterizations and overbroad generalizations. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

58. Denied. WMT denies the allegations in this Paragraph. By way of further answer, Plaintiffs' references to "Thin Shell" and "Thick Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

59. Denied. WMT denies the allegations in this Paragraph. Further, Plaintiffs' references to "Thin Shell" and "Thick Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

60. Denied. WMT denies the allegations in this Paragraph. Further, Plaintiffs' references to "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

F. Wright Belatedly Obtained (Post-Market) 510(k) Clearance for the Thin Shell.

61. Denied. WMT denies the allegations in this Paragraph. Further, Plaintiffs' references to "Thin Shell" are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

62. Denied. WMT denies the allegations in this Paragraph. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

63. Denied. WMT denies the allegations in this Paragraph. By way of further answer, this Paragraph contains conclusions of law to which no responsive pleading is required.

G. Wright Aggressively Marketed the Device as Appropriate for Active Patients.

64. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overgeneralizations.

65. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overgeneralizations.

66. Admitted in part; denied in part. WMT admits only that at times Jimmy Connors endorsed certain WMT hip devices. WMT denies all other allegations in this Paragraph as improper mischaracterizations.

67. Denied. WMT denies all allegations in this Paragraph and each sub-Paragraph. WMT specifically denies making any misrepresentations. Further, this Paragraph and each sub-Paragraph refers to written materials, the terms of which speak for themselves and any characterizations thereof or inferences made are denied.

68. Denied. WMT denies the allegations in this Paragraph. Further, this Paragraph refers to written materials, the terms of which speak for themselves and any characterizations thereof or inferences made are denied.

69. Denied. WMT denies the allegations in this Paragraph and each sub-Paragraph. Further, this Paragraph and each sub-Paragraph refers to written materials, the terms of which speak for themselves and any characterizations thereof or inferences made are denied.

70. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overgeneralizations.

71. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products allegedly at issue had “dangerously high revision rates.”

72. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overstatements.

73. Denied. WMT denies the allegations in this Paragraph.

74. Denied. WMT denies the allegations in this Paragraph.

75. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations.

H. Wright Minimized the Known Risk of Elevated Metal Ion Levels.

76. Denied. WMT denies the allegations in this Paragraph.

77. Denied. WMT denies the allegations in this Paragraph.

78. Denied. WMT denies the allegations in this Paragraph as improper misstatements and mischaracterizations.

79. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations.

80. Denied. WMT denies the allegations in this Paragraph.

81. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

82. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

83. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

84. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

85. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

86. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

87. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

88. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

89. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

90. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

91. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

92. Denied. WMT denies the allegations in this Paragraph.

93. Denied. WMT denies the allegations in this Paragraph.

94. Denied. WMT denies the allegations in this Paragraph.

95. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations.

96. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations.

97. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations and overbroad generalizations.

98. Denied. WMT denies the allegations in this Paragraph.

99. Denied. WMT denies the allegations in this Paragraph and specifically denies that it “falsely assuage[d] metal-ion concerns.”

100. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations.

101. Denied. WMT denies the allegations in this Paragraph.

102. Denied. WMT denies the allegations in this Paragraph.

103. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations.

I. Wright Studied Metal Ions Solely to Support A-Class Sales.

104. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations. Further, Plaintiffs’ references to “A-Class” are vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

105. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations. Further, Plaintiffs’ reference to “A-Class” is vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

106. Denied. WMT denies the allegations in this Paragraph. Further, this Paragraph refers to written materials, the terms of which speak for themselves and any characterizations

thereof or inferences made are denied. Moreover, Plaintiffs' reference to "A-Class" is vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

107. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations. Further, Plaintiffs' reference to "A-Class" is vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

108. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations. Further, Plaintiffs' reference to "A-Class" is vague, ambiguous, and undefined and WMT denies the averments in this Paragraph on that basis.

J. Wright's Representations and Reasonable/Justifiable Reliance.

109. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

110. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

111. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

112. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

113. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

114. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. WMT further specifically denies that the products alleged to be at issue were defective in any way.

115. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. WMT further specifically denies that the products alleged to be at issue were defective in any way.

116. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

117. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. WMT further specifically denies that the products alleged to be at issue were defective in any way.

118. Denied. WMT is without sufficient knowledge or information to form a belief as to what Plaintiff's physician may or may not be aware of regarding the devices allegedly at issue in this matter and therefore such allegations contained in this Paragraph are denied. WMT further specifically denies that the products alleged to be at issue were defective in any way.

119. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph regarding what physicians may or may not have done, and they are therefore denied. WMT denies all remaining allegations in this Paragraph as improper mischaracterizations and overbroad generalizations. WMT further specifically denies that the products alleged to be at issue were defective in any way.

120. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue had an "unacceptably high failure rate," or that the products alleged to be at issue were defective in any way.

121. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue had “high failure rates,” or that the products alleged to be at issue were defective in any way.

122. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

123. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue had “unacceptable failure rates” or that the products alleged to be at issue were defective in any way.

124. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

125. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

126. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue had “unacceptably high failure rates” or that the products alleged to be at issue were defective in any way.

127. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

128. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

129. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

130. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

131. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

132. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

133. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue had “high failure rates” or that the products alleged to be at issue were defective in any way.

134. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue had “high failure rates” or that the products alleged to be at issue were defective in any way.

K. Wright Ignored and Isolated Complaining Physicians.

135. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

136. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

137. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations.

138. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations. WMT specifically denies that its complaint department was “less-than-robust” or that the products alleged to be at issue were defective in any way.

139. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way.

140. Denied. WMT denies the allegations in this Paragraph as improper mischaracterizations, and specifically denies that the products alleged to be at issue were defective in any way. Further, this Paragraph refers to written materials, the terms of which speak for themselves, and any characterizations therefore or inferences made are denied.

PLAINTIFF’S INJURIES AND DAMAGES
PLAINTIFF PATRICIA POWELL’S CONSERVE® HIP

141. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

142. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

143. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and each sub-Paragraph and they are therefore denied. Further, this Paragraph, including each sub-Paragraph, contains conclusions of law to which no responsive pleading is required.

144. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

145. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

146. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

147. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

148. Admitted in part; denied in part. It is admitted only that at certain times WMT manufactured, distributed and sold in the United States certain prosthetic hip devices including those alleged to be at issue in this matter. WMT is without sufficient knowledge or information to form a belief as to the truth of the remaining averments contained in this Paragraph and each sub-Paragraph and they are therefore denied.

149. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further,

this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

150. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

151. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further, WMT specifically denies that the products alleged to be at issue were defective in any way.

152. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further, WMT specifically denies that the products alleged to be at issue were defective in any way.

153. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further, WMT specifically denies that the products alleged to be at issue were defective in any way.

154. Denied. WMT denies the allegations in this Paragraph. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

155. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further, WMT specifically denies that the products alleged to be at issue were defective in any way. Moreover, this Paragraph contains conclusions of law to which no responsive pleading is required.

156. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products allegedly at issue were defective in any way or that it was negligent in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

157. Denied. WMT denies the allegations in this Paragraph and each sub-Paragraph, and specifically denies that the products allegedly at issue were defective or unreasonably dangerous in any way. Further, this Paragraph and each sub-Paragraph contains conclusions of law to which no responsive pleading is required.

158. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were not properly tested.

159. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were not properly tested.

160. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were not properly tested.

161. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were not properly tested. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

162. Denied. WMT denies the allegations in this Paragraph.

163. Denied. WMT denies the allegations in this Paragraph and specifically denies that the Device alleged to be at issue “fail[ed] at higher than expected rates.”

164. Denied. WMT denies the allegations in this Paragraph and specifically denies that the Device alleged to be at issue “fail[ed] at higher than expected rates.”

165. Denied. WMT denies the allegations in this Paragraph and specifically denies that the Device alleged to be at issue failed “at higher than expected rates.”

166. Denied. As to the allegations regarding Plaintiff’s alleged injuries, WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. WMT denies the remaining allegations in this Paragraph and specifically denies that the products allegedly at issue were “unreasonably dangerous.”

167. Denied. WMT denies the allegations in this Paragraph and each sub-Paragraph. WMT specifically denies that the products alleged to be at issue were defective in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

FEDERAL STATUTORY AND REGULATORY REQUIREMENTS

168. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

169. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

170. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

171. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

172. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

173. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

174. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

175. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

176. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

177. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

178. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

179. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

180. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

181. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

182. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

183. Denied. This Paragraph, including each sub-Paragraph, contains conclusions of law to which no responsive pleading is required and they are therefore denied.

184. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

185. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

186. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

187. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

188. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

189. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

190. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

191. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

192. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

193. Denied. This Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

194. Denied. This Paragraph, including each sub-Paragraph, contains conclusions of law to which no responsive pleading is required and they are therefore denied.

195. Denied. WMT denies all allegations in this Paragraph and specifically denies that the products alleged to be at issue were adulterated. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

196. Denied. WMT denies all allegations in this Paragraph and specifically denies that the products alleged to be at issue were misbranded. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

197. Denied. WMT denies all allegations in this Paragraph and specifically denies that the products alleged to be at issue were adulterated. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

198. Denied. WMT denies the allegations in this Paragraph.

199. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were defective in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

200. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were not properly manufactured or designed. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

201. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were defective in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

202. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were unreasonably dangerous. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

203. Denied. WMT denies all allegations in this Paragraph. WMT specifically denies that the components allegedly at issue were or are defective in any way. Moreover, the allegations in this Paragraph are conclusions of law to which no responsive pleading is required and they are therefore denied.

LIABILITY

COUNT 1- NEGLIGENCE DESIGN AND FAILURE TO WARN OR INSTRUCT

204. WMT incorporates by reference its responses and denials to Paragraphs 1 through 203 of the Complaint as if fully set forth herein.

205. Admitted in part; denied in part. It is admitted only that at certain times, WMT designed, manufactured, assembled, inspected, tested, marketed, and/or sold certain orthopedic devices, including generally the medical devices allegedly received by Plaintiff and at issue in this matter. WMT specifically denies that any such devices were defective in any way. All other allegations in this Paragraph are denied. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

206. Denied. WMT denies the allegations in this Paragraph and specifically denies that the hip implant devices alleged to be at issue were defective or unreasonably unsafe in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

207. Denied. WMT denies the allegations in this Paragraph and specifically denies that the hip implant devices alleged to be at issue were defective in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

208. Denied. WMT denies the allegations in this Paragraph and specifically denies that the hip implant devices alleged to be at issue were defective in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

209. Denied. WMT denies the allegations in this Paragraph and specifically denies that the hip implant devices alleged to be at issue were defective in any way. Moreover, WMT specifically denies making any misrepresentations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

210. Denied. WMT denies the allegations in this Paragraph and specifically denies that the hip implant devices alleged to be at issue were not adequately tested. Moreover, WMT specifically denies making any misrepresentations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

211. Denied. WMT denies the allegations in this Paragraph and specifically denies that the hip implant devices alleged to be at issue were defective in any way. Moreover, WMT specifically denies making any misrepresentations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

212. Denied. WMT denies the allegations in this Paragraph and specifically denies that the hip implant devices alleged to be at issue were defective in any way. Moreover, WMT

specifically denies making any misrepresentations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

213. Denied. WMT denies the allegations in this Paragraph. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

214. Denied. WMT denies the allegations in this Paragraph. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

215. Denied. WMT denies the allegations in this Paragraph and specifically denies that the devices alleged to be at issue in this matter were defective in any way or that they failed to comply with federal requirements. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

216. Denied. WMT denies the allegations in this Paragraph. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

217. Denied. WMT denies the allegations in this Paragraph and specifically denies that it was negligent in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

218. Denied. WMT denies the allegations in this Paragraph and specifically denies that it was negligent in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

219. Denied. WMT denies the allegations in this Paragraph and specifically denies that it was negligent in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

220. Denied. WMT denies the allegations in this Paragraph and specifically denies that it was negligent in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

221. Denied. WMT denies the allegations in this Paragraph and specifically denies that it was negligent in any way, or that it engaged in “tortious conduct.” Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

WHEREFORE, having answered the allegations in the First Cause of Action, WMT requests that the Court enter judgment in its favor on the First Cause of Action and award any other relief the Court determines is just and proper.

COUNT 2- NEGLIGENT MISREPRESENTATION

222. WMT incorporates by reference its responses and denials to Paragraphs 1 through 203 of the Complaint as if fully set forth herein.

223. Denied. WMT denies the allegations in this Paragraph and specifically denies making any false or misleading representations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

224. Denied. WMT denies the allegations in this Paragraph and specifically denies making any misrepresentations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

225. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. WMT further specifically denies making any false or misleading representations.

226. Denied. WMT denies the allegations in this Paragraph and specifically denies making any misrepresentations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

WHEREFORE, having answered the allegations in the Second Cause of Action, WMT requests that the Court enter judgment in its favor on the Second Cause of Action and award any other relief the Court determines is just and proper.

COUNT 3- FRAUD BY CONCEALMENT

227. WMT incorporates by reference its responses and denials to Paragraphs 1 through 203 of the Complaint as if fully set forth herein.

228. Denied. WMT denies the allegations in this Paragraph. WMT specifically denies that that products alleged to be at issue were defective in any way or that it “deliberately failed to communicate” any information. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

229. Denied. WMT denies the allegations in this Paragraph. WMT specifically denies that that products alleged to be at issue were defective or unreasonably dangerous in any way, or that it concealed any information. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

230. Denied. WMT denies the allegations in this Paragraph and specifically denies that the products alleged to be at issue were defective in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

231. Denied. WMT denies the allegations in this Paragraph as misstatements of law, and specifically denies that the components alleged to be at issue were defective in any way. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

232. Denied. As to reliance by Plaintiff and/or her medical providers, WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. All other allegations in this Paragraph are denied. Further, this Paragraph contains conclusions of law to which no responsive pleading is required and they are therefore denied.

233. Denied. As to reliance by Plaintiff and/or her medical providers, WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph as to what Plaintiff and/or Plaintiff's physicians would have done, and they are therefore denied. All other allegations in this Paragraph are denied, and WMT specifically denies that it misrepresented or concealed any information.

234. Denied. WMT denies the allegations in this Paragraph and specifically denies that it concealed any information.

235. Denied. WMT denies the allegations in this Paragraph and specifically denies that it concealed any information. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

WHEREFORE, having answered the allegations in the Third Cause of Action, WMT requests that the Court enter judgment in its favor on the Third Cause of Action and award any other relief the Court determines is just and proper.

COUNT 4- FRAUDULENT MISREPRESENTATION

236. WMT incorporates by reference its responses and denials to Paragraphs 1 through 203 of the Complaint as if fully set forth herein.

237. Denied. WMT denies the allegations in this Paragraph and specifically denies that it made false representations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

238. Denied. WMT denies the allegations in this Paragraph and each sub-Paragraph. WMT specifically denies making any false representations or that the components alleged to be at issue were defective in any way. Further, this Paragraph and each sub-Paragraph refers to written materials, the terms of which speak for themselves and any characterizations thereof or inferences made are denied.

239. Denied. WMT denies the allegations in this Paragraph and specifically denies making false representations. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

240. Denied. WMT denies the allegations in this Paragraph and specifically denies making “false representations with the intent of defrauding and deceiving.” Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

241. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further,

WMT specifically denies making any false representations. Moreover, this Paragraph contains conclusions of law to which no responsive pleading is required.

242. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

243. Denied. WMT denies all allegations in this Paragraph. WMT specifically denies engaging in any fraudulent conduct. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

WHEREFORE, having answered the allegations in the Fourth Cause of Action, WMT requests that the Court enter judgment in its favor on the Fourth Cause of Action and award any other relief the Court determines is just and proper.

COUNT 5- LOSS OF CONSORTIUM

244. WMT incorporates by reference its responses and denials to Paragraphs 1 through 203 of the Complaint as if fully set forth herein.

245. Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied. Further, WMT specifically denies that the products alleged to be at issue were defective in any way.

244.² Denied. WMT is without sufficient knowledge or information to form a belief as to the truth of the averments contained in this Paragraph and they are therefore denied.

² Plaintiffs' Complaint began Count 5 with an allegation numbered "244," then it followed this allegation with allegations numbered, "245, 244, 245, and 246." For clarity, the Answer mirrors the Complaint.

245. Denied. WMT denies the allegations in this Paragraph and specifically denies that the components allegedly at issue were defective in any way or that it engaged in any “tortious conduct.” Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

246. Denied. WMT denies the allegations in this Paragraph. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

WHEREFORE, having answered the allegations in the Fifth Cause of Action, WMT requests that the Court enter judgment in its favor on the Fifth Cause of Action and award any other relief the Court determines is just and proper.

COUNT 6- PUNITIVE DAMAGES

247. WMT incorporates by reference its responses and denials to Paragraphs 1 through 203 of the Complaint as if fully set forth herein.

249.³ Denied. WMT denies all allegations in this Paragraph. Further, this Paragraph contains conclusions of law to which no responsive pleading is required.

WHEREFORE, having answered the allegations in the Sixth Cause of Action, WMT requests that the Court enter judgment in its favor on the Sixth Cause of Action and award any other relief the Court determines is just and proper.

WMT denies the allegations in the unnumbered Prayer for Relief Paragraph, and specifically denies that it is liable to Plaintiffs in any way.

³ Plaintiffs’ Complaint began Count 6 with an allegation numbered “247,” then it followed this allegation with an allegation numbered “249.” For clarity, the Answer mirrors the Complaint.

WMT denies any and all remaining allegations contained in Plaintiffs' Complaint not expressly admitted herein, including but not limited to any allegations contained in the headings and sub-headings in Plaintiffs' Complaint.

WHEREFORE, having responded fully to the allegations in the Complaint, WMT requests that the Court dismiss the Complaint in its entirety with prejudice, award WMT its costs and disbursements, including reasonable attorneys' fees, and grant all other relief the Court determines is just and proper.

JURY DEMAND

WMT hereby demands a trial by jury.

AFFIRMATIVE DEFENSES

WMT asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint may fail, in whole or part, to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' injuries or damages as alleged, if any, may have been caused, in whole or in part, by the acts or omissions of a third person or persons, which acts or omissions Wright Medical had no reason to anticipate and of which person or persons Wright Medical had no knowledge and over whom Wright Medical had no control.

THIRD AFFIRMATIVE DEFENSE

If there was a defect in and/or negligent sale of the medical device, an allegation that Wright Medical expressly denies, Wright Medical may not be liable because Wright Medical justifiably relied on the exercise of learned judgment of others in the regular course of the trade.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries or damages sustained, if any, may have been caused, in whole or part, by Plaintiffs' own negligence, and accordingly, Plaintiffs are barred in whole or in part, from recovery.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs knowingly and intentionally consented to and/or assumed any and all risks inherent in the use of the medical device when Plaintiffs proceeded to use the product having been fully informed of the risks and, therefore, Plaintiffs are barred from recovery.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred, in whole or in part, by Plaintiffs' failure to mitigate damages.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred, in whole or in part, because the medical device was at all relevant times manufactured and sold consistent with available technology, scientific knowledge, and the state of the art, and in compliance with all federal, state, and local laws and regulations, and was accompanied by product information and warnings that were reasonable, full and adequate and in accordance with FDA regulating requirements and the state of medical and scientific knowledge then in existence.

EIGHTH AFFIRMATIVE DEFENSE

If the medical device is unsafe in any way, it is unavoidably unsafe. Plaintiffs' purported action is, therefore, barred by Comment K of Section 402A of the Restatement (Second) of Torts and/or other applicable law.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries or damages sustained, if any, may be a direct and proximate result of a responsible, superseding, intervening cause.

TENTH AFFIRMATIVE DEFENSE

If Wright Medical is found responsible for causing the injuries or damages alleged in Plaintiffs' Complaint, the damages, if any, assessed against Wright Medical should be reduced in proportion to the percentage of fault, negligence, or responsibility attributable to Plaintiffs and all other responsible persons or entities.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statute of limitations, statute of repose, and/or by the equitable doctrines of laches and estoppel.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred by the doctrines of informed consent, release, and waiver.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred by the Learned Intermediary Doctrine.

FOURTEENTH AFFIRMATIVE DEFENSE

This case may be governed by the exclusive provisions of the Utah Product Liability Act, Utah Code Ann. § 78B-6-701, *et seq.* Any theories of recovery that fall outside of the Utah Product Liability Act are therefore subject to dismissal pursuant to Fed. R. Civ. P. 12(b)(6).

FIFTEENTH AFFIRMATIVE DEFENSE

Defendant asserts all allowable defenses under the Utah Product Liability Act, Utah Code Ann. § 78B-6-701, *et seq.*, including, but not limited to, the applicability of Utah Code Ann. §§ 78B-6-703, 78B-6-705, and 78B-6-706.

SIXTEENTH AFFIRMATIVE DEFENSE

Any damage that Plaintiffs sustained may have been caused by parties other than Wright Medical and over whom Wright Medical had no control.

SEVENTEENTH AFFIRMATIVE DEFENSE

Wright Medical alleges that the Complaint and the causes of action therein fail to state a legally enforceable action against Wright Medical because Plaintiffs' claims are preempted by the Federal Food, Drug and Cosmetic Act and regulations promulgated thereunder.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are preempted, in whole or in part, by the Federal Food, Drug and Cosmetic Act, the Medical Device Amendments thereto, and the Supremacy Clause of Article VI of the United States Constitution.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of deference to agency expertise and by the deference that the law gives to compliance with FDA regulations promulgated under the Food, Drug and Cosmetic Act, and the Medical Device Amendments thereto.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims fail, in whole or in part, pursuant to the applicability of Restatement (Third) of Torts: Product Liability §6(c) because the medical device is reasonably safe due to its

foreseeable therapeutic benefits, such that a reasonable health provider, knowing its foreseeable risks and benefits, would prescribe the device for any class of patients.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because there is no private right of action under the Federal Food, Drug and Cosmetic Act and the Medical Device Amendments thereto.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred, in whole or in part, on a theory of comparative negligence pursuant to Utah Code Ann. § 78B-5-818.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred, in whole or in part, pursuant to the applicability of Utah Code Ann. § 78B-2-307 and/or Utah Code Ann. § 78B-2-305.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Wright Medical asserts all allowable defenses under the Utah Truth in Advertising Act, Utah Code Ann. § 13-11a-1, *et seq.*, including, but not limited to, the applicability of Utah Code Ann. § 13-11a-5(1).

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Wright Medical asserts all allowable defenses under the Utah Consumer Sales Practices Act, Utah Code Ann. § 13-11-1, *et seq.*, including, but not limited to, the applicability of Utah Code Ann. § 13-11-22(1).

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are barred, in whole or in part, from recovering punitive and/or exemplary damages pursuant to the applicability of Utah Code Ann. §§ 78B-8-201 and 78B-8-203.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for punitive damages are barred by the applicable portions of the Constitution of the United States.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Pursuant to District of Utah Civil Rule 9-1 and Utah Code Ann. §§ 78B-5-817 through 78B-5-823, WMT hereby reserves the right to allocate fault to non-parties.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSES

WMT does not presently know all of the facts and circumstances respecting Plaintiffs' claims. WMT reserves the right to amend and/or supplement this Answer should WMT later discover facts demonstrating the existence of additional defenses.

Dated: June 24, 2020

Respectfully submitted,

/s/ Elisabeth M. McOmber

Elisabeth M. McOmber

Jason R. Harmon

SNELL & WILMER

*Attorney for Defendant Wright Medical Technology,
Inc.*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 24th day of June 2020, a true and correct copy of the foregoing document was filed and served electronically via the Court's ECF system on the following counsel of record:

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